

# Kelly's Medical

*for your family, home & health*

EQUIPMENT  
& SUPPLY

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August 4, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20857

Re: Docket NOS. 92N-0297 and 88N-0258

Dear Sir or Madam:

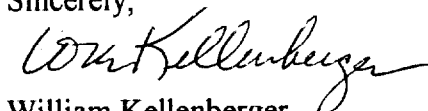
We purchase pharmaceuticals from a small wholesale distributor who buys from a full-line wholesaler. We also buy needles and other medical items that will fall within this ruling. I understand the FDA is requiring much more extensive prescription sales history information than has been required under the 1988 FDA Guidance on this issue that wholesalers have followed for the past 12 years. As a result, the reseller I buy from will be unable to sell directly to me because of the tracing problems created.

The direct wholesalers we have contacted require monthly minimum purchases of \$15,000 up to \$50,000. We do not buy anything near these figures. This means my costs will increase and so my retail prices will have to increase. I don't expect Medicare and Medicaid to increase their reimbursement on drugs and other items affected by this new regulation. Therefore, I expect to lose 100% of this business due to government over-regulation.

This arrangement will be true for all medical supply dealers. The only ones that will survive are the national companies who fill all their prescriptions from California or New Jersey or some other central location. It will all be mail order. Is this the type of service you want for you and your family?

Finally, I would like to protest that this rule is being changed without notification to the companies it will affect the most – the small business. If I had not accidentally run across an internet posting of this rule change, I would not be aware of it today. To really know how this will affect the small business, notices of this change have to be sent to those companies being affected. Otherwise its like making a law that all clothing stores must track the manufacturer-middle man-wholesaler-distributor-retailer of each piece of clothing so we know it did not involve child labor, without telling the retailers that this will be required. This is big government using a big stick on small business.

Sincerely,



William Kellenberger  
Owner

88N-0258

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